GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4138
ANSWERED ON:20.04.2005
COMPAIGN AGAINST COMPANIES MANUFACTURING SPURIOUS DRUGS
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether a campaign has been launched in the country to identify the companies manufacturing spurious drugs ;

(b) if so, the outcome thereof;

(c) whether these spurious drugs are mostly prescribed by quacks practicing in rural and urban areas as they get huge commission on these drugs; and

(d) if so, the steps being taken by the Government to effectively check the same?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE(SMT. PANABAKA LAKSHMI)

(a) to (d) : Being a clandestine activity, it is difficult to assess the actual quantum of spurious drugs. However, as per the information available from the State Drug Controllers, 38824, 43138 and 40862 drugs samples were tested during the period 2001-02, 2002-03 and 2003-04 out of which 96, 129 and 118 samples respectively were found spurious which is 0.33%, 0.29% and 0.288% of the samples reported spurious.

The figures quoted by media range from 10% to 25% of drugs in the country being spurious/counterfeit drugs. These seem to be unsubstantiated reports. On the basis of an alleged WHO report, the media frequently reports that 35% of fake drugs produced in the world come from India. However, when enquired, the WHO has neither confirmed its authenticity nor the source of such figures.

No such study has been carried out through which it may be substantiated that quacks practicing in rural and urban areas mostly prescribe spurious drugs as they get huge commission on these drugs. Under the provisions of Drugs and Cosmetics Act and Rules thereunder, it is the responsibility of State Governments through their respective Drug Control organizations to regulate manufacture and sale of drugs as well as to keep a surveillance over possible movement of spurious/counterfeit drugs. Trading in counterfeit product including drugs is reported world over. However, keeping in view the serious implications of spurious drugs on public health as well as the loss to genuine industry, the Govt. has taken various measures to combat this menace.

(i) Detailed guidelines have been issued to the State Govts. to undertake focused surveillance over possible movement of spurious drugs.

(ii) A Capacity Building Project through World Bank assistance has been taken up to provide substantial assistance to State Govts. to upgrade drug testing facilities or to establish new drug testing laboratories.

It is expected to increase the number of samples tested in the country from about 36,000 samples to 1,00,000 samples per year and to reduce the reporting time to less than a month as against the present period from 3 to 6 months.

(iii) Specific training programme for regulatory officials of State Govts. on logistics of intelligence work, prosecutions etc. has been conducted with the assistance of FDA, Maharashtra. This activity is proposed to be continued.

(iv) In order to ensure efficient information exchange between drug regulatory officers in the country, in respect of licensing, sampling, prosecution, etc., a countrywide computer networking project has been undertaken by the Central Govt. This will enable the Central Govt. to regularly monitor the enforcement activities and recommend corrective measures.

(v) Pharma industry and trade has been motivated to fight menace of spurious drugs as a shared responsibility. No. of cases could be successfully detected through the initiative taken by Pharma industry involving hiring of retired intelligence officers.

(vi) Since the success of eradicating the menace of spurious drugs depends upon adequate measures taken by State Govts., HFM took up this issue in October 2002 in detail with all Chief Ministers.

a. A meeting of Health Ministers of all major States was especially convened in November 2002 to ensure the action to check the menace of spurious drugs. The views emerged in the meeting have been communicated to all State Govts. in January 2003 for implementation.

(vii) The recommendation of Mashelkar Committee which was constituted by the Government in 2003, to examine all aspects relating to the drug regulatory system in the country including the problem of spurious/sub standard drugs, are being followed for necessary change in legislation as well as improvement of enforcement activities.

A Bill was introduced in the Lok Sabha in December 2003, to amend the said Act to provide stricter penalties to the offenders including a maximum penalty of capital punishment. It also provided for making the offences non-bailable and cognizable and for designated courts for speedy trial of cases. The Bill lapsed with the dissolution of the 13th Lok Sabha and is in the process of being re-introduced in Parliament with some modifications.